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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/038,694	12/31/2001	Jeff T. Hutchins	07083.0008U5	1998

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EXAMINER

SNEDDEN, SHERIDAN

ART UNIT

PAPER NUMBER

1653

DATE MAILED: 04/06/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/038,694	Applicant(s) HUTCHINS ET AL.	
	Examiner Sheridan K. Snedden	Art Unit 1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 February 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 9-19 is/are pending in the application.
- 4a) Of the above claim(s) none is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 9-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 1/27/05
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Response to Amendment

1. This Office Action is in response to Paper filed 2/2/2005. Claims 1-8 and 20-80 have been canceled. Applicant's amendment of claim 11 is acknowledged. Claims 9-19 are under examination.

Withdrawal of Objections and Rejections

2. All prior objections and/or rejections are withdrawn in lieu of the following.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 11-19 are rejected under 35 U.S.C. 102(e) as anticipated by Turner *et al.* (US 2002/0137894 A1). As Turner *et al.* does not provide express examples of each embodiment encompassed by the claims, the claims are rejected in the alternative, under 35 U.S.C. 103(a) as obvious over Turner *et al.* (US 2002/0137894 A1).

Turner *et al.* teach recombinant or genetically engineered MSFs for intracellular expression in a bacterial host, such as *E. coli* (section [0045]). As a matter of fact, MSF is referenced in the art as SZP and proteoglycan 4 (see for example, Ikegawa *et al.* (IDS)).

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The MSF proteins and the DNA sequences encoding MSFs of Turner *et al.* can be produced via recombinant genetic engineering techniques and purified from a mammalian cell line which has been designed to secrete or express the MSF to enable large quantity production of pure, active MSFs useful for therapeutic applications. The proteins may also be expressed in bacterial cells, e.g., *E. coli*, and purified therefrom. SZP purified from *E. coli* would not be glycosylated. The proteins may also be expressed and purified in yeast cells or in baculovirus or insect cells (see section [0107]), in which case, SZP would be glycosylated. Claim 18 is directed to an inherent property of SZP and is included in this rejection.

At section [0124], Turner et al. teach that once the MSF is expressed by the transformed and cultured cells, it is then recovered, isolated and purified from the culture medium (or from the cell, if expressed intracellularly) by appropriate means known to one of skill in the art.

At section [0125], Turner et al. teach a preferred purification procedure to isolate a recombinant MSF from serum free mammalian cell (COS-1) conditioned medium (regarding claim 19).

Thus, the reference anticipates the invention, or at least provides the requisite motivation to perform the invention as recited in the claims.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 9-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Flannery *et al.* (IDS) in view of Adkisson *et al.* (US 6645764 B1).

Flannery *et al.* teach that SZP is a proteoglycan specifically produced by chondrocytes. Flannery *et al.* teach SZP purified from bovine chondrocytes cultured in 5% solution of serum. The cells were cultured, the media harvested and the SZP was purified (see page 536, last paragraph). Flannery does not teach the use of serum free media.

It would have been obvious to a person of ordinary skill in the art to culture chondrocytes grown under serum-free conditions for purposes of purifying SZP as taught in Flannery *et al.* Adkisson provides several motivations for culturing chondrocytes under serum-free conditions.

1) Chondrocytes grown under serum-free conditions to day 120 produce hyaline tissue that is roughly 1.5-2 mm thick. Wet weights of 300-400 mg were obtained from material grown in 12 well dishes (FIGS. 1A and 1B). The structural characteristics of this hyaline cartilage mimics that of native articular cartilage.

2) Chondrocytes grown under the specified serum-free conditions go through the same number of doublings as those cells grown in the presence of serum (See Fig. 2).

3) Chondrocytes grown under serum-free conditions produced at least 10-fold greater amounts of proteoglycan (sulfated glycosaminoglycan) and more than 2-fold greater levels of collagen (hydroxyproline) as compared to parallel cultures that were maintained in 10% FBS (See Fig 3).

Thus, the claimed invention was within the ordinary skill in the art to make and use at the time it was made and was as a whole, *prima facie* obvious.

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Conclusion

6. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sheridan K Snedden whose telephone number is (571) 272-0959.

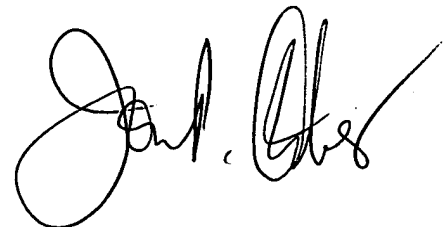
The examiner can normally be reached on Monday - Friday, 8:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on (571) 272-0925. The fax phone number for regular communications to the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

SKS
March 21, 2005

SKS

A handwritten signature in black ink, appearing to read 'Jon Weber', with a large, stylized initial 'J' and a checkmark-like flourish at the end.

**JON WEBER
SUPERVISORY PATENT EXAMINER**